

Changes of amended claims

Claim 1

Line 1 change "chemopreventing craving" to treating alcohol craving

Claim 2

Line 1 change "The method" to A method of treating alcohol craving

Claim 3

Line 1 add of treating alcohol craving between method and as

Claim 4

Line 1 add of treating alcohol craving between method and as

Claim 5

Line 1 add of treating alcohol craving between method and as

Claim 6

Line 1 add of treating alcohol craving between method and as

Claim 7

Line 1 change "orally administering a composition producing alcohol like effects in a beverage designed to look and taste like" to treating alcohol craving by orally administering an anticraving composition of matter, that produces the effects of alcohol in a beverage designed to look and taste as

treating alcohol craving by orally administering an  
aniticraving composition of matter that produces the effects  
of alcohol in a beverage designed to look and taste as

Claim 8

Delete claim 8

Claim 9

Line 1 change "as defined by claim 7, comprising a non-  
alcoholic wine." To of treating alcohol craving as defined  
by claim 7, comprising a wine which has the alcohol removed  
and replaced by kavapyrones.

Claim 10

Line 1 change "as defined by claim 7, comprising a non-  
alcoholic distilled spirit." To of treating alcohol craving  
as defined by claim 7, comprising a distilled spirit which  
has the alcohol removed and replaced by kavapyrones.

Response to office action summary and explanation of claims modification

Item #2 Page 3

Claims amended with the statement "A method of treating alcohol craving"

Item #3 Page 3

Claims amended with the statement "A method of treating alcohol craving"

Item #5 Page 4

The Claims as amended describe the use of a beverage that has no alcohol but looks, tastes and feels as an alcoholic beverage in order to motivate the addict to drink the beverage in his normal social setting while effectively treating his addiction. A major tenant of alcohol addiction treatment is the requirement of the addict needs to avoid places and people associated with his addiction. This sacrifice is often more that the addict is able to make and addiction treatment fails. This invention uses anticraving compounds in a carrier medium appropriate to the alcoholic's social setting and habits and leads to compliance and ultimately sobriety. According to this invention the addict changes nothing about his life. The addict can maintain his friends and socialize with people drinking alcohol while drinking kava wine or kava mixed drinks that are actively treating his craving for alcohol.

Item #6 Page 4

Claims amended with the removal of "like"

Item #7 Page 4

Claims amended with the removal of "non-alcoholic distilled spirit" and replaced with "distilled spirit which has the alcohol removed and replaced by kavapyrones"

Item #9 Page 5

Chatterjee has patented the method of using a proprietary kava extract "WS 1490" specifically for the use as an antianxiety agent after the patients were give two weeks of

benzodiazepines for anxiety. Chatterjee has patented the method of using kava as an antianxiety agent only after the patients had previously been prescribed benzodiazepines and as a substitute for benzodiazepines in the treatment of anxiety. Chatterjee further clarifies that the kava extract WS 1490 was tested only on patients for the reduction of anxiety. He reports a reduction in the Hamilton anxiety score. At no time did Chatterjee state that the extract WS 1490 was used to reduce the patients craving for the substance of abuse. At no time did Chatterjee imply that the extract WS 1490 was intended to reduce the patient's desire for the substance of abuse. At no time did Chatterjee test the extract WS 1490 for the potential of the extract to reduce or eliminate the intake of the substance of abuse. At no time did Chatterjee imply that the extract could be used for the treatment of addictions. Chatterjee only used the extract on patients who were already abstinent and suffering withdrawal symptoms for the sole purpose of reducing the anxiety associated with withdrawal.

The current patent application by Steiner patents the method of using kavapyrones for the purpose of reducing craving for alcohol for the sole purpose of facilitating abstinence from alcohol. Steiner tested kavapyrones on long term alcoholics in a double blind study and found a statistically significant reduction in alcohol consumption and statically significant increase in alcohol abstinence. Steiner has performed and documented the use of kavapyrones for reducing craving to alcohol and has documented successful treatment of alcohol addiction with the use of kavapyrones.

Many compounds have been patented for the treatment of symptoms of a disease and later are patented as a new use for the treatment of the disease. A case in point is ibuprofen. Ibuprofen was patented and has known anti-inflammatory, antipyretic and analgesic properties. However, ibuprofen was patented in 1987 (US 4701470) for the treatment of herpes. Many other examples of this same situation exist where a compound is patented to treat a symptom and latter patented to treat the disease when this finding is made. Chatterjee has patented kava for treating the anxiety associated with withdrawal. Chatterjee has not patented kava for the treatment of addiction. Chatterjee does not propose kava can be used to treat craving or addictions.

#### Item #10

Cody has patented the use of the combination of Plantago Major and Piper Methysticum for the treatment of addiction to tobacco or nicotine. Cody states on page 2 line 32 that it is Plantago major that is the herb that is used as a

deterrent to tobacco consumption. He further states that Plantago major causes an aversion to tobacco. On page 3 line 13 he further clarifies that tobacco aversion is the same thing as reducing the craving for tobacco. On page 4 line 4 Cody clearly states that Plantago major is used as an anticraving agent for tobacco and Piper methysticum is used for its antidepressive and antianxiety properties. Cody and Chatterjee clearly are using kavapyrones as antianxiety agents. Cody is using kava as an antianxiety agent in combination with Plantago major. Chatterjee is using kava extracts as an antianxiety agent following the use of benzodiazepines. Both Cody and Chatterjee have used kavapyrones as a method to reduce the anxiety associated with addictions. Neither Cody or Chatterjee have used or suggested kavapyrones have any anticraving properties. Neither Cody nor Chatterjee suggests that kavapyrones have any ability to reduce craving or treat addictions.

Item #11 Page 5

Cody claims the use of kava formulations for treating anxiety associated with nicotine withdrawal using tables and capsules. Steiner does not claim the use of kava formations for the treatment of nicotine withdrawal anxiety.

Item #12 Page 5

Giles claims a method of using the combination of Caffeine and kava to suppress appetite. On page 3 line 60 Giles proposes that kava reduces appetite by reducing anxiety and anesthetizing the stomach. At no time does Giles claim Kava is an anticraving agent. At no time does Giles claim that kava treats craving. At no time does Giles claim that kava has the ability to treat addiction to alcohol. Steiner claims kava is an anticraving agent for alcohol and does not claim that kava suppresses appetite. Giles, Cody and Chatterjee use kava as an antianxiety agent.

Item # 13 Page 6

Current amended claims do not claim non-alcoholic beer compositions comprising kava.

Item # 14 Page 6

Many drinks have been formulated that include kava. Different beverages include small amounts of kava as herbal additives. However, no one has suggested kava be added to non-alcoholic wine or distilled spirits. Replacing alcohol

in wine and distilled spirits is novel and has proven effective as a method of motivating alcohol addicts to consume an adequate amount of kava to reduce their craving and permit them to reach sobriety.

One of the primary reasons treatment of alcoholism fails and relapse occurs is because the addict is required to avoid the people and places associated with alcohol. Often this is a major part of the addict's life, which he finds too much to give up. By providing a substitute for alcohol that can replace the alcohol without requiring the addict to give up his friends or the act of drinking has proven to be an important part of this invention. When the anticraving agent looks, tastes and feels as an alcoholic beverage this feature encourages the addict to consume the anticraving agent when he needs it the most. The addict finds he can maintain his current friendships and social structure at the same time he is motivated to consume the anticraving agent. This novel feature leads to greater compliance and ultimately sobriety. The method of substituting the anticraving compounds for alcohol is a significant and novel aspect of this invention. Kavakaze is a herbal beverage that only intends to produce a beverage that serves to relax the consumer and is not intended to be a substitute for alcohol in a wine or a distilled spirit and is not intended for the treatment of addictions.

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'134 does not teach kava formulations for treating withdrawal for drugs or alcohol as outlined previously. '134 teaches the use of kava as an antianxiety agent for the treatment of anxiety after the patient is already abstinent.

'825 does not teach kava formulations for treating nicotine. '825 teaches the use of kava as an antianxiety agent to treat the anxiety associated with withdrawal for tobacco. '825 teaches the use of another herb as an anticraving agent for tobacco. Steiner does not claim kava as an anticraving agent for tobacco.

'363 does not teach treatment of hunger craving. '363 never states kava treats craving. '363 states the kava is an antianxiety agent and may anesthetize the stomach. '363 teaches caffeine and kava is effective in combination in order to suppress appetite. Steiner does not teach kava is an appetite suppressant.

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'134 does not teach kava formulations for treating withdrawal for drugs or alcohol as outlined previously. '134 teaches the use of kava as an antianxiety agent for the treatment of anxiety after the patient is already abstinent.

'825 does not teach kava formulations for treating nicotine. '825 teaches the use of kava as an antianxiety agent to treat the anxiety associated with withdrawal for tobacco. '825 teaches the use of another herb as an anticraving agent for tobacco. Steiner does not claim kava as an anticraving agent for tobacco.

'363 does not teach treatment of hunger craving. '363 never states kava treats craving. '363 states the kava is an antianxiety agent and may anesthetize the stomach. '363 teaches caffeine and kava is effective in combination in order to suppress appetite. Steiner does not teach kava is an appetite suppressant.

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Bunz and Kavakaze do not teach wine or distilled spirits with the alcohol removed and replaced by kavapyrones.

The use of non-alcoholic wine or distilled spirits as a critical motivating factor for the treatment of addiction is not obvious.

Sincerely,

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